Fuzhou Chunlan Medical Equipment Co.,Ltd

CONTENTS

Manufacturer profile

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Manufacturer profile

Fuzhou Chunlan Medical Devices Co., Ltd.

In 2007, our company be recruited from Nantong, Jiangsu, to build a factory for production. In 2009, Yongtai Branch of Fuzhou Chunlan Medical Instrument Co., Ltd. was established as the production location. The main production and operation was of multi-cavity catheter, 6866 medical consumables. The company has been working in the medical device industry for more than ten years. Factory facilities are complete. There are Class 100,000 purification workshops, Class 10,000 first class clean testing rooms, medical purified water, ethylene oxide sterilization, and product testing, etc. During this epidemic, Chun Lan, with the strong support of the government, was converted into a mask manufacturer and was one of the first companies to obtain a temporary registration number for Fujian Machinery. Let's not forget the original goal, keep in mind the mission, and move on.

Business license

Medical device manufacturer

统一社会信用代码

91350116919378702

营业执照

（副 本） 副本编号：1－1

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　福州春风医疗器械有限公司

类　　型　有限责任公司

法定代表人　黄春章

经营范围　保健用品、包装材料的研究开发；建筑材料、装饰材料的批发、零售、代购代销；货物的进出口，但国家限定公司经营或禁止进出口的商品和技术除外；其他未列明的医疗设备及器械制造；医疗器械销售；生产、销售医用防护口罩；生产、销售非医用防护口罩。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　壹佰贰拾捌万圆整

成立日期　2009年08月13日

营业期限　2009年08月13日 至 长期

住　　所　福州市晋安区鼓山镇福兴大道3号福晟大厦5F08－55

登记机关　福州市晋安区市场监督管理局

2020 年 7 月 14 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

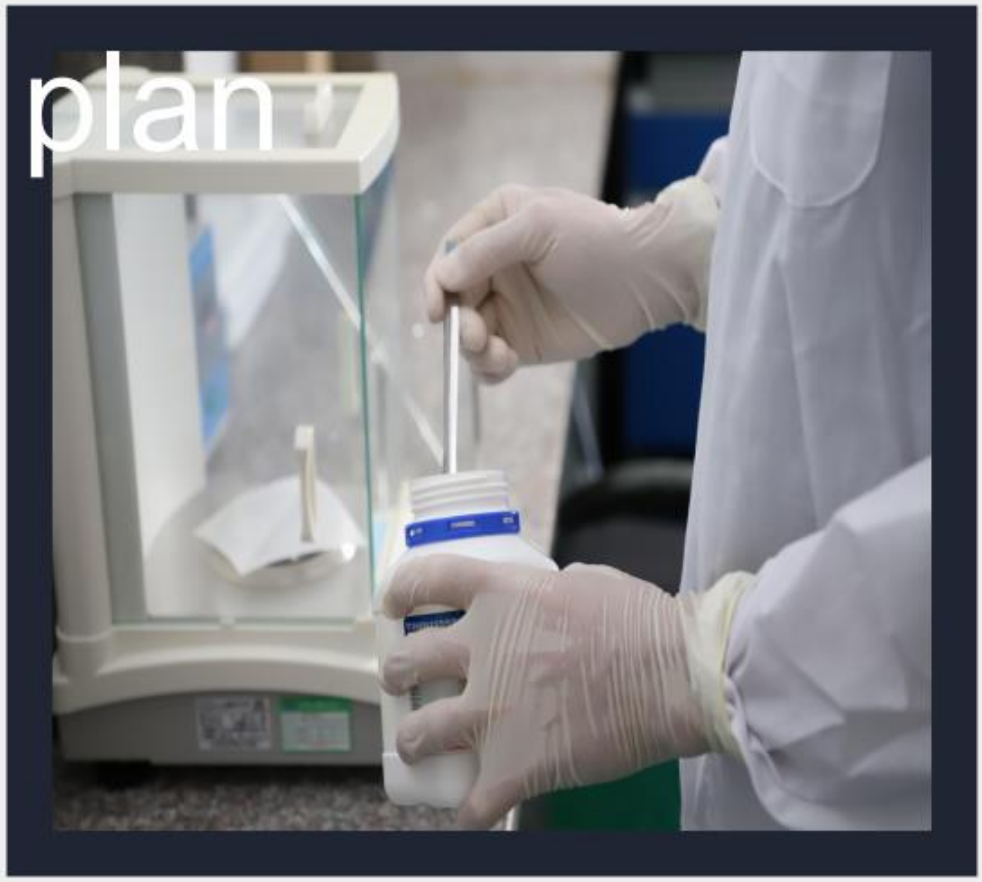
市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告

国家市场监督管理总局监制

Quality control plan

Procurement, production, inspection, sales

The device is manufactured in compliance with ISO13485: Medical Devices – Quality Management Systems – Requirements for an equivalent quality system and the manufacturer has documentation of such.



Manufacturer view

Product show 2

Folding Respirator

Europe

FFP2

EN149：2001+A1：2009

NB2163

02

USA
FDA EUA

N95

EN149：2001+A1：2009
&
Fluid resistance testing(GB 19083-2010)

01

China

Kn95

GB2626-2006

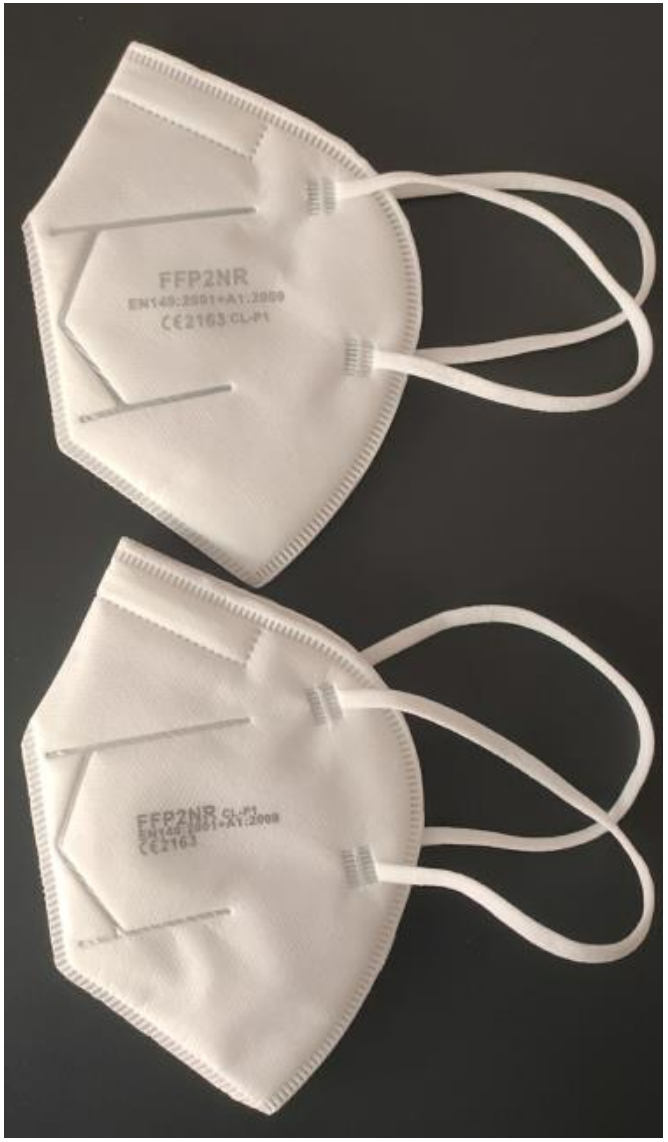
03


CE2163
EN149:2001+A1:2009
FFP2 NO.2163-PPE-901
Modello: CL-P1
Semi-maschere filtranti
contro le particelle


CE 2163
Chunlan
CL-P1
FFP2 NR
Fliering Half Mask
Natural skin friendly
Strengthen protection
Non-Medical
10pcs


合格证
Certification
FFP2
Foglietto illustrativo
Modello:CL-P1
Semi-maschere filtranti
contro le particelle
FFP2
Uso singolo
Modello:CL-P1
CE2163 EN 149:2001+A1:2009
FFP2


CE 2163
Chunlan
FFP2


FFP2NR
EN149:2001+A1:2009
CE2163 CL-P1


CE2163
EN149:2001+A1:2009
FFP2NR CL-P1

Surgical N95 respirator(EUA)

Model NO.CL-P1

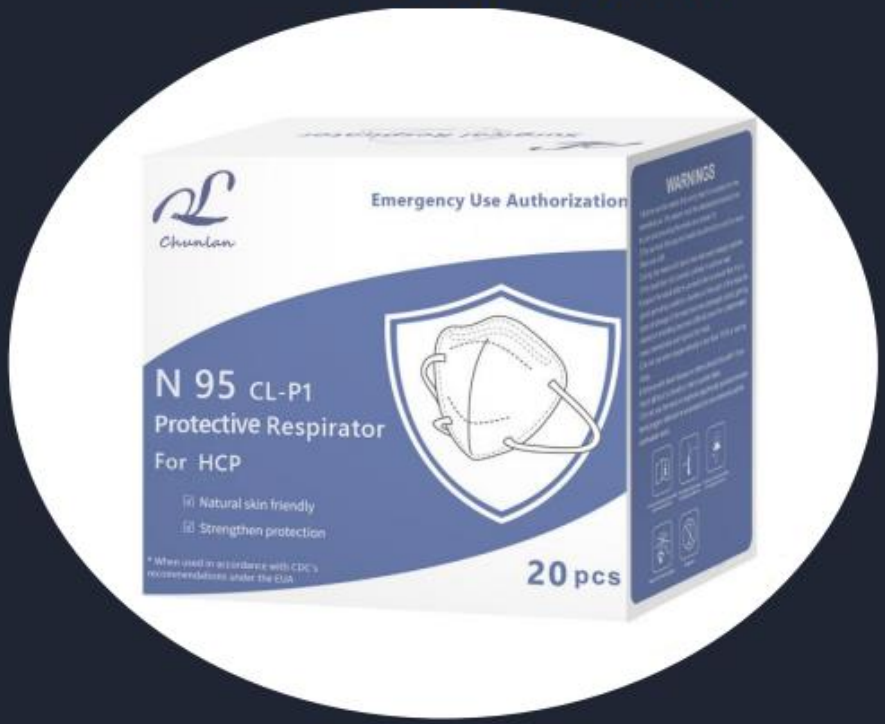
[Primary Structure]

This product consists of a respirator body, a nose clip,a sponge nose strip and two elastic earloop;the respirator body is made of four-layer cloth--PP non-woven fabrics,Melt blown non-woven fabrics etc.

[Use Range]

Effectively filter air non-oily and oily particles. It can filter PM2.5 and is suitable for resisting oily particles in automobile exhaust.During the COVID19,that FDA has authorized that health care professionals the emergency use of the device in the hospital.

145*90*130 mm



N95 package

Folding Respirator

Europe

FFP2

EN149：2001+A1：2009

NB2163

02

USA
FDA EUA

N95

EN149：2001+A1：2009
&
Fluid resistance testing(GB 19083-2010)

01

China

Kn95

GB2626-2006

03

FFP2

[Product Name] Filtering half mask

[Standard] EN149：2001+A1：2009

[Model No.] CL-P1

Folding Respirator

Europe

FFP2

EN149：2001+A1：2009

NB2163

02

USA
FDA EUA

N95

EN149：2001+A1：2009
&
Fluid resistance testing(GB 19083-2010)

01

China

Kn95

GB2626-2006

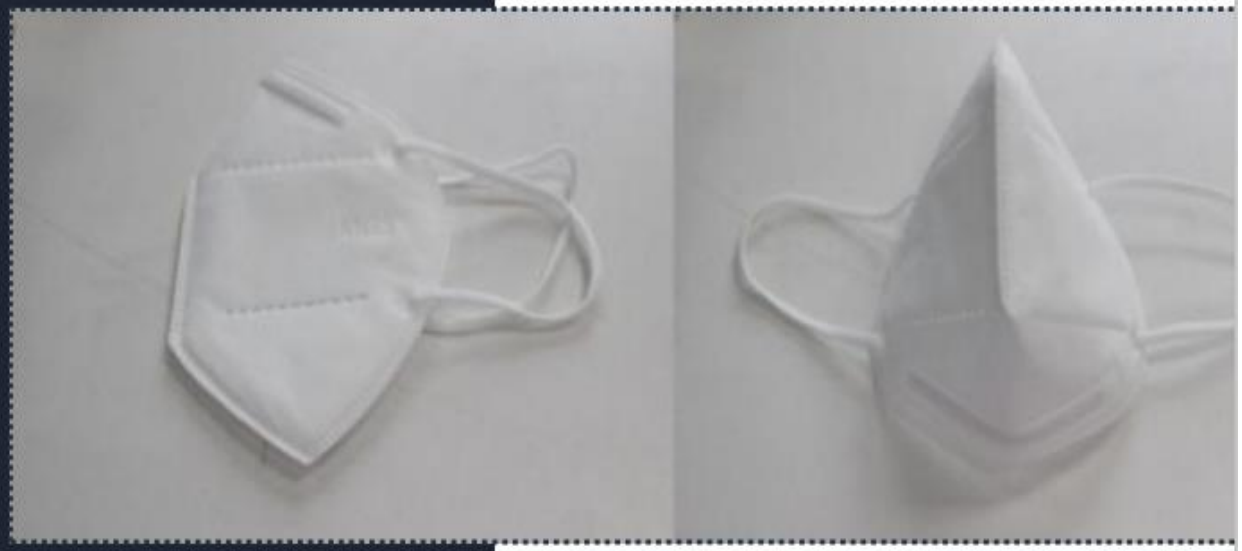
03

KN95

[Product Name] KN95 Filtering Half Mask

[Standard] GB2626-2006

[Model No.] CL-P2



Disaposal flat mask

1

Disposable medical mask

<Color> Blue-white
<Quantity> 50 pcs
<Standar> YY/T 0969-2013

2

Disposable daily protective mask

<Color> Blue-white
<Quantity> 50 pcs
<Standar> GB/T 32610-2016

3

Disposable children

<Color> different
<Quantity> 50 pcs
<Standar> GB/T 38880-2020


Certification
3

N95 FDA EUA

FDA U.S. FOOD & DRUG ADMINISTRATION

July 21, 2020

Fuzhou Chunlan Medical Equipment Co., Ltd.
5F08-55, Fusheng Building, No. 3 Fuxing Avenue,
Gushan Town, Jin'an District, Fuzhou City,
Fujian, China 350700

EUA201972

Re: FFRs Made in China

Dear Chen Xiaohui:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator model CL-P1 as an authorized respirator to the Emergency Use Authorization (EUA) for non-NIOSH-approved filtering facepiece respirators manufactured in China[1], which was revised and reissued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) on June 6, 2020. We have reviewed your request to be added to Appendix A of this EUA and determined that model included meets the eligibility criteria in the June 6, 2020 EUA for non-NIOSH approved respirators made in China. As such, your respirator(s) is hereby added to Appendix A as an authorized respirator.

Having concluded that the eligibility criteria are met, I am adding your respirators to Appendix A, as described in the Scope of Authorization (Section II). As such, these respirator models are authorized for use by healthcare personnel in healthcare settings in accordance with CDC recommendations and subject to the Conditions of Authorization (Section IV) of the attached letter. We remind you that, among other things, you are required to meet the following labeling requirements:

Manufacturers

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the

[1] The EUA Letter of Authorization is available at, https://www.fda.gov/media/136664/download.

FDA U.S. FOOD & DRUG ADMINISTRATION

authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

Additionally, please be advised that if your firm does not have the appropriate fluid resistance testing, the respirator should not be labeled as "surgical."

Import information can be found on the Information for Filing Personal Protective Equipment and Medical Devices During COVID-19 page. If you need to resolve entry issues for shipments, please contact 301-796-0356 or COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Sincerely,

Suzanne B. Schwartz -S

Digitally signed by Suzanne B. Schwartz -S
Date: 2020.07.21 11:05:41 -04'00'

Suzanne Schwartz, MD, MBA
Deputy Director (& Acting Office Director)
Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

CE

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-901

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Fuzhou Chunlan Medical Equipment Co., Ltd.
5F08-55, Fusheng Building, No. 3 Fuxing Avenue, Gushan Town, Jin'an District, Fuzhou City, Fujian Province, China
are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Model: CL-P1
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfillment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

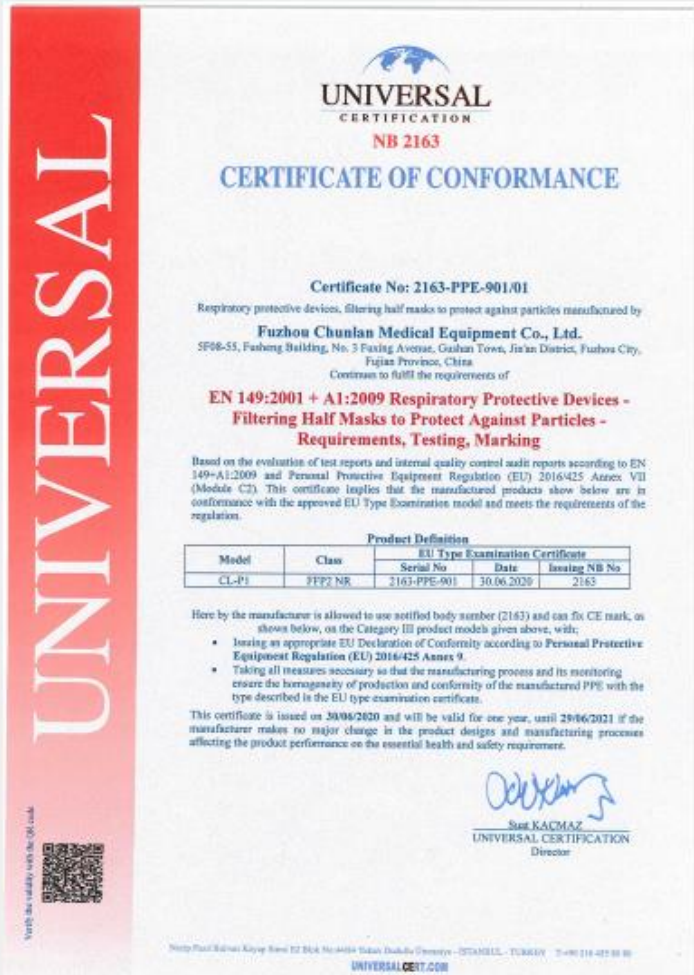
This certificate is initially issued on **30/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSALCERT.COM



UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-901/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Fuzhou Chunlan Medical Equipment Co., Ltd.
5F08-55, Fusheng Building, No. 3 Fuxing Avenue, Gushan Town, Jin'an District, Fuzhou City, Fujian Province, China
Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
CL-P1	FFP2 NR	2163-PPE-901	30.06.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

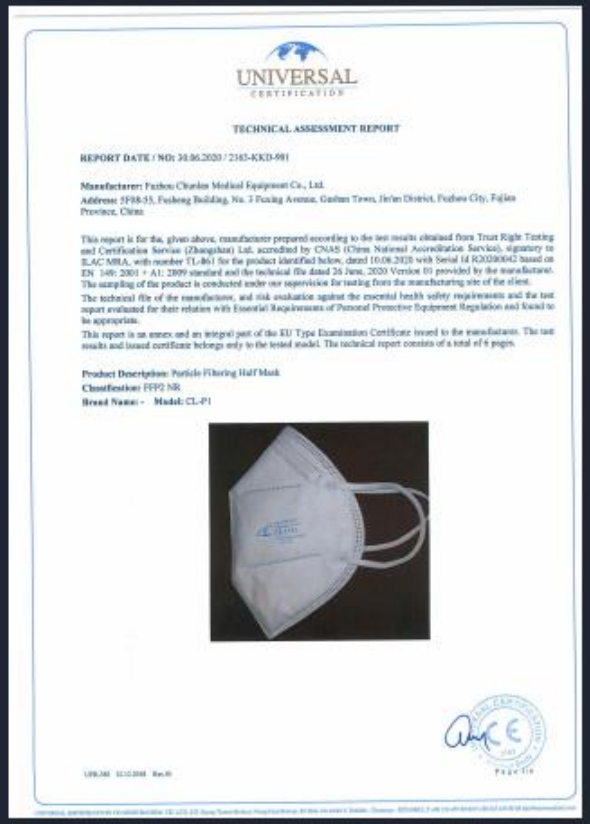
This certificate is issued on **30/06/2020** and will be valid for one year, until **29/06/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

UNIVERSALCERT.COM

CE testing report



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CERTIFICATION

TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 30.06.2020 / 2163-KKD-981

Manufacturer: Fuzhou Chenlan Medical Equipment Co., Ltd.
Address: 5F08-55, Fusheng Building, No. 3 Fuxing Avenue, Gushan Town, Jin'an District, Fuzhou City, Fujian Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from Trust Right Testing and Certification Service (Zhangzhou) Ltd. accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number TL-861 for the product identified below, dated 10.06.2020 with Serial Id R20200042 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 26 June, 2020 Version 01 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.
The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personal Protective Equipment Regulation and found to be appropriate.
This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask
Classification: FFP2 NR
Brand Name: - Model: CL-P1

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ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

1.1. Design principles
1.1.1. Ergonomics
PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest possible level.

1.1.2. Levels and classes of protection
1.1.2.1. Highest level of protection possible
The optimum level of protection to be taken into account in the design is that beyond which the constraints felt by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk
Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE
1.2.1. Absence of risks and other inherent nuisance factors
PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

1.2.1.1. Suitable constituent materials
The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user
Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

1.2.1.3. Maximum permissible user impediment
Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

1.3 Comfort and effectiveness
1.3.1. Adaptation of PPE to user morphology
PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and design strength
PPE must be as light as possible without prejudicing design strength and efficiency.
Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.

1.4. Information supplied by the manufacturer
The notes that must be drawn up by the framer and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorised representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performances as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any mark/signote 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE.

These notes, which must be precise and comprehensible, must be provided at least in the official languageor of the member state of destination.

UNIVERSAL
CERTIFICATION

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems
If PPE incorporates adjustment systems, The latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

2.3. PPE for the face, eyes and respiratory tystem
Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimized.
The screens for these types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.
If necessary, such PPE must be treated or provided with means to prevent misting-up.
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing
If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
If the manufacturer is unable to give an undertaking with regard to the useful life of PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions

2.6. PPE for use in potentially explosive atmosphere
PPE intended for use in potentially explosive atmosphere must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

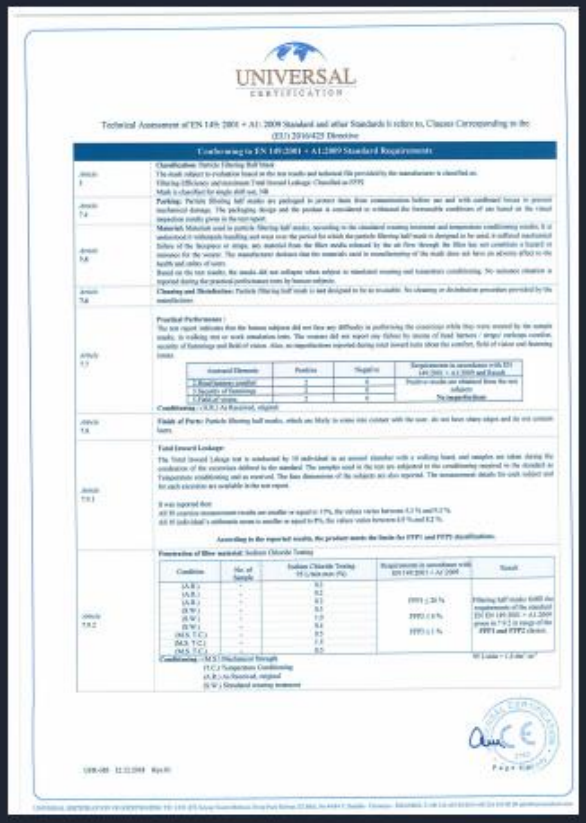
2.8. PPE for intervention in very dangerous situations
The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret these and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user
Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety
The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeabluseful life of the PPE. In addition, these marks must be complete, concise and comprehensible so as to prevent any misinterpretation. In particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow all he part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS
3.10.1. Respiratory protection
PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed in a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.
The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.
The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to ensure appropriate low resistance and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.
The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.
In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filter units in their original packaging.

CE testing report



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CERTIFICATION

Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards in relate to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements

Article 3 — **Classification:** Particle Filtering Half Mask
The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as:
Filtering efficiency and maximum Total Inward Leakage: Classified as FFP2
Mask is classified for single shift use, NR

Article 7.4 — **Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with sufficient forces to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.

Article 5.8 — **Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results, it is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse effect to the health and safety of users.
Based on the test results, the masks did not collapse when subject to simulated wearing and temperature conditioning. No intrinsic situation is reported during the practical performance tests by human subjects.

Article 7.6 — **Cleaning and Disinfection:** Particle filtering half mask is not designed to be re-useable. No cleaning or disinfection procedure provided by the manufacturer.

Article 5.3 — **Practical Performance :**
The test report indicates that the human subjects did not face any difficulty in performing the exercises while they were assisted by the remote results, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also, no imperfections reported during total inward leak tests about the comfort, field of vision and fastening issues

Assessed Elements	Positive	Negative	Requirement in accordance with EN 149:2001 + A1:2009 and Result
1. Head harness comfort	9	0	Positive results are obtained from the test subjects No imperfections
2. Security of Fastenings	9	0	
3. Field of vision	9	0	

Conditioning : (A.R.) As Received, original.

Article 7.8 — **Fields of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.

Article 7.9.3 — **Total Inward Leakage:**
The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking board, and samples are taken during the conduction of the exercises defined in the standard. The samples used in the test are subjected to the conditioning required in the checklist as Temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each exercises are available in the test report.

It was reported that:
All 10 exercise measurement results are smaller or equal to 11%, the values varies between 0,3 % and 9,3 %
All 10 individual's arithmetic means is smaller or equal to 8%, the values varies between 0,9 % and 8,2 %.

According to the reported results, the product meets the limits for FFP1 and FFP2 classifications.

Article 7.9.2 — **Penetration of filter material:** Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing % (max.mean (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,3	FFP1 ≤ 20 %	Filtering half masks fulfil the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in stage of the FFP1, FFP2 classes.
(A.R.)	-	0,2		
(A.R.)	-	0,3		
(S.W.)	-	0,5		
(S.W.)	-	7,9	FFP2 ≤ 6 %	
(S.W.)	-	9,4		
(M.S. T.C.)	-	0,5	FFP3 ≤ 1 %	
(M.S. T.C.)	-	1,1		
(M.S. T.C.)	-	0,5		

Conditioning : (M.S) Mechanical Strength
(T.C) Temperature Conditioning
(A.R) As Received, original
(S.W) Simulated wearing treatment

Article 7.10 — **Compatibility with skin:** In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

Article 7.11 — **Flammability :**

Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	Burn for 0s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfil requirements of the standard
(A.R.)	-	Burn for 0s		
(T.C.)	-	Burn for 0s		
(T.C.)	-	Burn for 0s		

Conditioning : (A.R.) As Received, original
(T.C.) Temperature Conditioning

Article 7.12 — **Carbon dioxide content of the inhalation air:**

Condition	No. of Sample	CO2 content of the inhalation air (%)(by volume)	As a average CO2 content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,05	0,18 (%)	CO2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfil requirements of the standard
(A.R.)	-	0,27			
(A.R.)	-	0,18			

Conditioning : (A.R) As Received, original

Article 7.13 — **Head harness:** In Practical Performance and T.S. test reports no adverse effects have been reported for donning and removal of the mask after the results of those tests indicates that the test loops / head harness are capable of holding the mask firmly enough.

Article 7.14 — **Field of vision:** In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is worned.

Article 7.15 — **Exhalation Valve(s):** The model under inspection have no valves.

Article 7.16 — **Breathing Resistance: Inhalation**
The overall evaluation in the figure gathered for 9 different samples 3 as received, 3 with temperature conditioning and 3 simulated wearing treatment conditioned samples with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min

Passed.

UNIVERSAL
CERTIFICATION

Article 7.17 — **Clogging:** This test is not applied to Particle Filtering Half Mask, which is not reusable.

Article 7.18 — **Demountable Parts:** There are no demountable parts on the product.

Article 8 — **Testing:** All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask.

Article 9 — **Marking – Packaging:** Necessary markings are available on the product package (box). The manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001 + A1:2009 standard, the end date of shelf life, sizing and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex F.1 of the Industrial file.

The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing CL-PT. The mask template (drawing) indicates that the mask will carry information about the manufacturer / Authorized Chambers of the manufacturer, Type of mask, the reference to EN 149:+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mark do not have rib-assemblies. From the tested sample by this laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model CL-PT drawing exhibit in the technical file of the manufacturer, Annex 8 of technical file.

Article 10 — **Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, instructions installation instructions/ pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate, Annex 8. The manufacturer shall include this documented user information even in every smallest commercially available package.

PREPARED BY	APPROVED BY
Ozmir CAMCI PPE Expert	Sait KAÇMAZ Director

19083–2010 CNAS testing report

佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co.,Ltd.(Foshan)

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：2376296857
报告编号(Report No)：ZFLJ2618380	Page 2 of 4

--- Test Result (测试结果) ---

	Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
1. Basic Requirement(口罩基本要求) *GB 19083-2010 Section 5.1(见本标准 5.1)*			
Result(测试结果)	Accordance（符合）	The mask should cover the nose and mouth of the wearer,should have good face-seal, the surface shall not have holes, Besmirch, should not have exhalation valve.(口罩应覆盖佩戴者的口鼻部，应有良好的面部密合性，表面不得有破损、污渍，不应有呼气阀。)	Pass(合格)
2. Nose Clip(鼻夹) *GB 19083-2010 Section 5.2(见本标准 5.2)*			
Result(测试结果)	Accordance（符合）	The mask shall be fitted with a nose clip.（口罩上应配有鼻夹。）	Pass(合格)
	Accordance（符合）	Nose clip shall be adjustable.(鼻夹应具有可调节性。)	
3. Mask Belt(口罩带) *GB 19083-2010 Section 5.3(见本标准 5.3)*			
Result(测试结果)	Accordance（符合）	The mask belt should be easy to adjust and with sufficient strength to fix mask position.(口罩带应调节方便,应有足够强度固定口罩位置。)	Pass(合格)
The tensile strength of the connection point between the mask belt and the mask body (口罩带与口罩体连接点处的断裂强力)>10N		The tensile strength of the connection point between the mask belt and the mask body (口罩带与口罩体连接点处的断裂强力) ≥ 10N	
4. Filtration Efficiency(过滤效率) *GB 19083-2010 Section 5.4(见本标准 5.4)*			
Unit(单位): <%>			
Result(测试结果)	98.1	Level 1(1 级)≥ 95	Pass(合格)

佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co.,Ltd.(Foshan)

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：2376296857
报告编号(Report No)：ZFLJ2618380	Page 3 of 4

	Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
5. Resistance to Penetration by Synthetic Blood(合成血液穿透) *GB 19083-2010 Section 5.5(见本标准 5.5)*			
Synthetic blood surface tension: 0.040N/m, Pressure: 10.7kPa, Use a fixed target.（合成血液表面张力：0.040N/m，压力：10.7kPa，使用定靶板）			
Result(测试结果)	No penetration（未渗透）	There should be no penetration on the inside of the mask(口罩内侧不应出现渗透)	Pass(合格)
6. Determination of resistance to surface wetting(表面抗湿性) *GB/T 4745-1997 Spray test(喷淋法)*			
The temperature of the used water is 20.8℃.(测试用水温度为20.8℃)			
Unit(单位): **<grade(级)>**			
Specimen 1#(样品 1#) 3-4 Specimen 2#(样品 2#) 3-4 Specimen 3#(样品 3#) 3-4		≥ 3	Pass(合格)
7. Airflow Resistance(气流阻力) *GB 19083-2010 Section 5.4(见本标准 5.4)*			
Air flow: 85L/min, Aerosol:NaCl(气体流量：85L/min，气溶胶物质：NaCl)			
Unit(单位): **<Pa>**			
Result(测试结果)	126.7	≤ 343.2	Pass(合格)
8. Flammability(阻燃性能) *GB 19083-2010 Section 5.9(见本标准 5.9)*			
Unit(单位): **<s>**			
Afterflame time(续燃时间)	0	Afterflame time(续燃时间)≤ 5	Pass(合格)

佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co.,Ltd.(Foshan)

检 测 报 告(Testing Report)	防伪查询网址(Security website)：www.fcl-sz.org.cn 防伪码(Security code)：2376296857
报告编号(Report No)：ZFLJ2618380	Page 1 of 4

Applicant Information (客户信息)

Applicant Name(委托单位) : Fuzhou Chunlan Medical Equipment Co., Ltd.(福州春岚医疗器械有限公司)
Applicant Address(委托单位地址) :5F08-55, Fusheng Building, No.3 Fuxing Avenue, Gushan Town, Jin'an District, Fuzhou City, Fujian Province(福州市晋安区鼓山镇福兴大道 3 号福诚大厦 5F08-55)
Manufacturer(生产单位) : 无(福州春岚医疗器械有限公司永泰分公司)

Sample Information (样品信息)

Sample Description(样品描述) : Protective face mask for medical use (医用防护口罩)
Sample Quantity(样品数量) : 32 pieces(32 个)
Colour and Description (颜色及描述):White, Folding ear loop (白色，折叠耳挂式)
Material Components (原料成分) : spunbond non-woven , spunlace, melt blown non-woven (纺粘无纺布，水刺布，熔喷无纺布)

- Sample Receiving date (收到样品的日期) : 2020-04-30
- Report date (报告日期) : 2020-05-10
- The original sample is sticked on the last paper. (送检样品原样粘贴在本报告的末页)

Test Performed (检验标准)

Judgement according to(评定依据):
GB 19083-2010 Technical requirements for protective face mask for medical use 医用防护口罩技术要求
- Selected test(s) as requested by applicants. (本实验室根据客户要求完成以下检测内容)

Pronounce (声明)

The results shown in this report refer only to sample(s) tested unless otherwise stated.All the items are performed in the standard conditions, except the noted cases (除非特别说明，测试结果只对来样负责。所有测试项目均在标准规定的环境下进行，特注明除外。)
Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account.(除非客户要求，本报告检测结果及符合性判定不考虑测量结果的不确定度。)

Signed for and on behalf of
CNTAC Testing Service Co.,Ltd.(Foshan)
Approved by
（批准）

KN95 CNAS testing report

CMA 180011112242

检 验 报 告

TEST REPORT

报告编号 REPORT NO.	国纺委字第 W202015369 号
产品名称 NAME OF SAMPLE	KN95 白吸过滤防颗粒呼吸器
委托单位 CUSTOMER	福州春岚医疗器械有限公司
检验类别 TEST CATEGORY	委托检验

浙江省轻工业品质量检验研究院

（浙江省纺织测试研究院）

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

Zhejiang Light Industrial Products Inspection and Research Institute
National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

Test report

Number:W202015369E page1/3

Name of Customer	Fuzhou Chunlan Medical Equipment Co., Ltd.	Address	SF08-55, Fusheng Building, No.3 Faxing Avenue, Gushan Town, Jin'an District, Fuzhou City, Fujian Province
Manufacturer	Fuzhou Chunlan Medical Equipment Co., Ltd.	Address	SF08-55, Fusheng Building, No.3 Faxing Avenue, Gushan Town, Jin'an District, Fuzhou City, Fujian Province
Sample information	Name of sample: Disposable respirator face mask Characteristics of sample: White Trademark of sample: —— Specification/model: —— Level: KN95 Category of safety specification: —— Art. No.: ——		
Above-mentioned information by Customer-supplied			
The sent way of sample	Courier	Sample quantity	30 pieces
Receiving Date of Sample	2020/05/05	Test Category	Entrusted inspection
Date of Testing	2020-05-05~ 2020-05-13		
Rating&Requirements	GB 2626-2006		
Test Summary: See the attached page for the results.			
Remarks			

Approved by:

Date of Approval: 2020-05-13

Test report

Number:W202015369E page2/3

ITEM	STANDARD (KN95)	RESULT	RATING
1. FILTER EFFICIENCY(SALT MEDIUM) (GB 2626-2006 6.3)(%)			
-	≥95.0	99.2	PASS
2. RESPIRATORY RESISTANCE (GB 2626-2006 6.5 & 6.6)(Pa)			
-INSPIRATORY RESISTANCE	≤350	183	PASS
-EXPIRATORY RESISTANCE	≤250	164	PASS
3. HEADBAND (GB 2626-2006 6.11)			
-	10N,hold on 10s，no breakage or slippage	No breakage or slippage were observed	PASS
4. APPEARANCE (GB 2626-2006 6.1 & 6.2)			
-	Meet the requirements of GB 2626-2006 standard	The appearance quality of 2 masks conforms to the standard	PASS
5.VISUAL FIELD BELOW MASK (GB 2890-2009)(°)			
-	≥60	78	PASS

Medical device registration certificate &
Medical device production license

医疗器械生产许可证

许可证编号：闽药监械生产许20200040号（临时）

企业名称：福州春岚医疗器械有限公司

生产地址：永泰县梧桐镇坂埕工业区

法定代表人：黄学匡

生产范围：二类14-14医护人员防护用品***

企业负责人：黄学匡

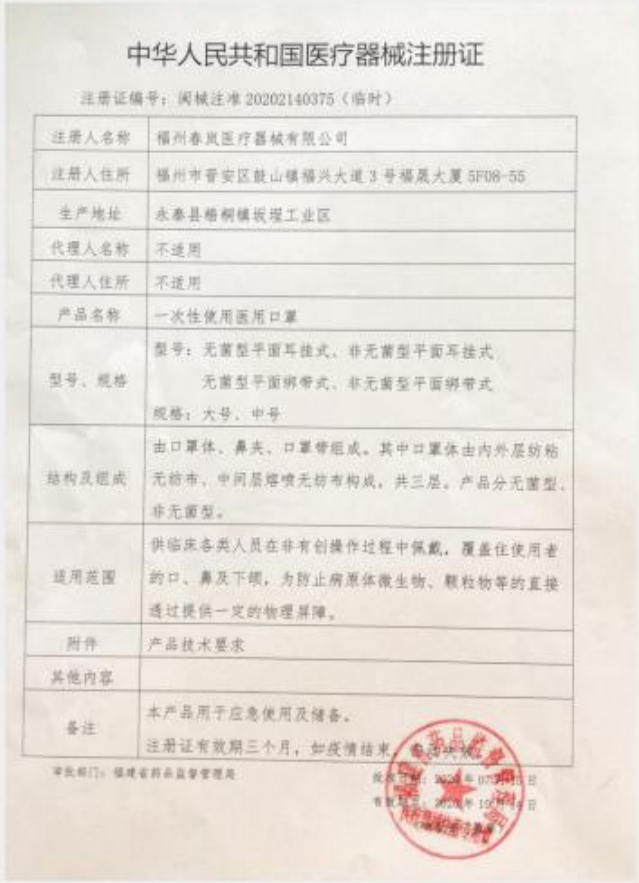
住　　所：福州市晋安区鼓山镇福兴大道3号福晟大厦5F08-55

发证部门：福建省药品监督管理局

有效期限：至　2020　年　10　月　14日

发证日期：2020　年　07　月　15　日

国家药品监督管理局制



中华人民共和国医疗器械注册证

注册证编号：闽械注准 20202140375（临时）

注册人名称	福州春岚医疗器械有限公司
注册人住所	福州市晋安区鼓山镇福兴大道3号福晟大厦5F08-55
生产地址	永泰县梧桐镇坂埕工业区
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩
型号、规格	型号：无菌型平面耳挂式、非无菌型平面耳挂式 无菌型平面绑带式、非无菌型平面绑带式 规格：大号、中号
结构及组成	由口罩体、鼻夹、口罩带组成。其中口罩体由内外层纺粘无纺布，中间层熔喷无纺布构成，共三层。产品分无菌型、非无菌型。
适用范围	供临床各类人员在非有创操作过程中佩戴，覆盖住使用者的口、鼻及下颌，为防止病原体微生物、颗粒物等的直接透过提供一定的物理屏障。
附件	产品技术要求
其他内容	
备注	本产品用于应急使用及储备。 注册证有效期三个月，如疫情结束，[illegible]

审批部门：福建省药品监督管理局

批准日期：2020年07月15日

有效期至：2020年10月14日

Disposable medical mask testing report

福建省医疗器械与药品包装材料检验所

检 验 报 告 首 页

报告编号：YX20203029　　共 3 页 第 1 页

样品名称	一次性使用医用口罩 抽样（ ） 送样（ √ ）	样品编号	YX20203029
规格	/	型号规格	无菌型平面耳挂式（大号）
委托方	福州春风医疗器械有限公司	检验类别	出厂补充检验
委托方地址	福州市永泰县经济开发区 10 号	产品编号/批号	20200523
生产单位	福州春风医疗器械有限公司	抽样单编号	——
供样单位	福州春风医疗器械有限公司	生产日期	/
抽样基数	——	样品数量	150
抽样日期	——	检验地点	本检验所实验室
收样日期	2020-06-06	检验日期	2020-06-09
检验项目	全项目（除外观、结构与尺寸）		
检验依据	福州春风医疗器械有限公司《一次性使用医用口罩》产品技术要求		
检验结论	被检样品所检项目符合福州春风医疗器械有限公司《一次性使用医用口罩》产品技术要求。 （检验检测专用章或检验单位公章） 签发日期：2020-07-03		
备注	1）报告中的“——”表示此项不适用，报告中的“/”表示此项空白； 2）微生物指标由福建省食品药品质量检验研究院检验； 3）附件 1：医疗器械产品技术要求预评价意见； 4）附件 2：福州春风医疗器械有限公司《一次性使用医用口罩》产品技术要求。		

授权人签字：[illegible]　　职务：副所长

福建省医疗器械与药品包装材料检验所

检 验 报 告

报告编号：YX20203029　　共 3 页 第 2 页

序号	检验项目	标准条款		标准要求	检验结果	单项结论
1	鼻夹	5.5	5.5.1	口罩上应配有鼻夹，鼻夹由可塑性材料制成	符合要求	符合
			5.5.2	鼻夹长度应不小于 8.0cm	10.2cm～10.4cm	
2	口罩带	5.4	5.4.1	口罩带应能取下使	符合要求	符合
			5.4.2	每根口罩带与口罩体连接点处的断裂强力应不小于 10 N	符合要求	
3	细菌过滤效率（BFE）	5.9		口罩的细菌过滤效率应不小于 95%	大于 98%	符合
4	颗气阻力	5.8		口罩两侧压差与气体交换的颗气阻力应不大于 49Pa/cm²	29Pa/cm²～35Pa/cm²	符合
5	微生物指标	5.7	——	非无菌型口罩应符合表 3 的要求： 细菌菌落总数≤1000CFU/g； 大肠菌群，不得检出； 绿脓杆菌，不得检出； 金黄色葡萄球菌，不得检出； 溶血性链球菌，不得检出； 真菌，不得检出	—— ——	符合
			5.7.2	无菌型口罩应无菌	无菌生长	
6	无菌型口罩环氧乙烷残留量	5.8		环氧乙烷残留应不超过 10μg/g	小于 1μg/g	符合
	以下空白					

福建省医疗器械与药品包装材料检验所

检验报告照片页

报告编号：YX20203026　　共 3 页 第 3 页

照片和说明

样品描述

检验说明：

型号规格或其他说明

型号规格：无菌型平面耳挂式（大号）

Disposable flat daily protective mask testing report

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 W202009609 号　　第 1 页 共 3 页

委托单位名称 Name of Customer	福州参美医疗器械有限公司	地 址 Address	福建省福州市晋安区鼓山镇软兴大道 3 号福晟大厦 1F08-5S
生产单位 Manufacturer	福州参美医疗器械有限公司	地 址 Address	福建省福州市晋安区鼓山镇软兴大道 3 号福晟大厦 1F08-5S
样品信息 Sample information	样品名称 Name of sample：一次性使用口罩 样品特性 Characteristics：蓝色 商标 Trademark：—— 规格/型号 Specification/model：—— 等 级 Level：—— 安全技术类别 Category of safety specification：—— 样品款号/货号 Art. No.：——		
以上为委托信息（Above mentioned information by Customer supplied）			
采样方式 The sent way of sample	快递	样品数量 Sample quantity	2K 只
送检日期 Receiving Date of Sample	2020-04-23	检测类别 Test Category	委托检验
判定依据 Basis/Requirements	GB/T 32610-2016		

检测结论/Test Summary：

实测结果详见报表。

检测日期：自 2020-04-23 至 2020-05-01

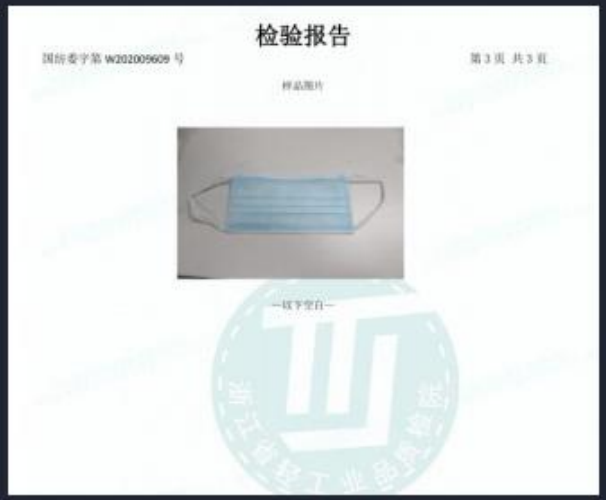
备 注 Remarks	样品标注类别/防护级别/规格，按标准要求 B 级判定。

签 发：Approved by 曹丽勤

检验报告

国纺委字第 W202009609 号　　第 2 页 共 3 页

序号	检测项目		检测方法	单位	标准要求（B 级）	实测值	单项评价	结果备注
1	甲醛含量		GB/T 2912.1-2009	mg/kg	≤20	未检出	符合	检出限：20mg/kg
2	pH 值（最高层）		GB/T 7573-2009	——	4.0～8.5	6.6	符合	萃取液：KCl
3	可分解致癌芳香胺染料		GB/T 17592-2011，GB20401-2010 6.8	mg/kg	禁用	未检出	符合	检出限：5mg/kg
4	耐干摩擦色牢度		GB/T 29866-2013	级	≥4	4-5	符合	——
5	耐湿摩擦色牢度		GB/T 29865-2013	级	≥4	4-5	符合	——
6	呼吸阻力	吸气阻力	GB/T 32610-2016	Pa	≤175	78	符合	——
		呼气阻力		Pa	≤145	59		
7	口罩各层以及口罩与口罩体的连接处断裂强力		GB/T 32610-2016	N	≥20	53	符合	——
8	过滤效率（盐性介质）		GB/T 32610-2016 附录 A	%	≥90	90.2	符合	——
9	防护效果		GB/T 32610-2016 附录 B	%	≥65	74.9	符合	——
10	口罩下方视野		GB 2890-2009 6.8	°	≥60	78	符合	——
11	外观质量		GB/T 32610-2016 6.1	——	符合 GB/T32610-2016 标准要求	10 个口罩的外观质量符合标准	符合	——



检验报告

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样品图片

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FDA registration

2020

CERTIFICATE OF REGISTRATION

This Certifies that:

FUZHOU CHUNLAN MEDICAL EQUIPMENT CO.,LTD.

5F08-55,Fusheng Building,No.3 Fuxing Avenue,Gushan Town, Jin'an District, Fuzhou City, Fujian, 350700, CHINA

Was registered with US Food & Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807. Such registration has been verified, with the registrant's authorization, by Ningbo SEC Testing Technology Co., Ltd.

Owner/Operator Number :10069189

Listing Number	Product Code(s)	Device Name	Proprietary Name
D398065	QKR	Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Ile Guidance	(Mask)

Issued: Apr. 11, 2020

Expiration Date: Dec. 31, 2020

This Certificate affirms that Ningbo SEC Testing Technology Co., Ltd has verified that the above stated facility is registered with the US Food & Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807.39, on the date stated above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. Ningbo SEC Testing Technology Co., Ltd. assume no liability to any person or entity in connection with the foregoing. Ningbo SEC Testing Technology Co., Ltd. is a private registration agent and is not affiliated with the US Food and Drug Administration.

Ningbo SEC Testing Technology Co., Ltd.
CHINA OFFICE: 400-615-6268
Web: http://www.fda.gov

Director

Establishment Registration & Device Listing

FDA Home ◎ Medical Devices ◎ Databases

1 result found for **Owner Operator Number :**
10069189

New Search

Establishment Name	Registration Number	Current Registration Yr
FUZHOU CHUNLAN MEDICAL EQUIPMENT CO.,LTD CHINA	No number listed	2020
• Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Ile Guidance - Mask		Foreign Exporter; Manufacturer

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THANKS